

REMARKS

Applicants respectfully requests entry of the amendments and remarks submitted herein. Claim 1 is amended herein to remove the recitation of an ICOS amino acid sequence consisting of a fragment of at least 15 amino acids of the extracellular domain, and to add the term "second" to part (b)(III) of the claim. Support for this amendment can be found, for example, in claims 24-26. In addition, claim 26 is amended herein to recite that the peptide sequence unrelated to the ICOS or the second peptide sequence unrelated to ICOS is an immunoglobulin CH2-CH3 sequence. Support for this amendment can be found in Applicants' specification at, for example, page 18, lines 18-20, which disclose that an ICOSIg polypeptide was produced by linking sequences encoding the ICOS extracellular domain to a CH2-CH3 sequence. Thus, no new matter has been added.

In light of the following remarks, Applicants respectfully request reconsideration and allowance of claims 1, 3-7, and 24-26.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1, 3-7, and 24-26 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Examiner stated that the recitation of "B7-H2" is indefinite because its identity is unclear. The Examiner asserted that the name "B7-H2" is also used to designate a different B7-related protein, and thus a person having ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicants respectfully disagree. According to M.P.E.P § 2173.02, the definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the particular application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. The C.A.F.C. has stated that the test for definiteness under 35 U.S.C. § 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). A person of ordinary skill in the art, reading Applicant's specification, would understand what is meant by "B7-H2" as recited in the present claims. This

is particularly true given that the specification at page 23, lines 4-7 discloses that the human B7-H2 polypeptide used in the experiments described is that whose sequence is depicted in the Wang *et al.* reference [(2000) *Blood* 96:2808-2813]. Thus, the metes and bounds of the recited polypeptides are clear, and the present claims are definite.

In light of the above, Applicants respectfully request withdrawal of the rejection of claims 1, 3-7, and 24-26 under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1, 3-7, and 24-26 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter. The Examiner asserted that the specification does not provide sufficient support for the recitation of “a fragment of at least 15 amino acids” or “a fragment [. . .] of the extracellular domain” (emphasis in original).

Applicants respectfully disagree. The specification provides support for fragments of at least 15 amino acids of the ICOS extracellular domain as previously recited in claim 1. To further prosecution, however, Applicants have removed the recitation of “a fragment of at least 15 amino acids of the extracellular domain” from claim 1.

In light of this amendment, Applicants respectfully request withdrawal of this rejection of claims 1, 3-7, and 24-26 under 35 U.S.C. § 112, first paragraph.

Claim 26 stands rejected under 35 U.S.C. §112, first paragraph, as allegedly containing new matter. The Examiner asserted that the recitation of an “immunoglobulin Fc fragment” represents a departure from the specification and claims as originally filed.

Applicants respectfully disagree. The specification provides support for the phrase “immunoglobulin Fc fragment” recited in claim 26 as previously presented. To further prosecution, however, Applicants have amended claim 26 to recite “an immunoglobulin CH2-CH3 sequence.” This phrase is fully supported by Applicant’s specification. See, for example, page 18, lines 18-20, which disclose an ICOSIg polypeptide containing an ICOS extracellular domain and a CH2-CH3 sequence.

In light of this amendment, Applicants respectfully request withdrawal of this rejection of claim 26 under 35 U.S.C. § 112, first paragraph.

Claims 1, 3, 5, 7, and 24-26 stand rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement. The Examiner asserted that the specification provides enablement for a variant of an amino acid sequence consisting of an extracellular domain of wild-type ICOS, but does not reasonably provide enablement for a variant of a wild type ICOS amino acid sequence consisting of a fragment of at least 15 amino acids of the extracellular domain. The Examiner also asserted that since the specification discloses that the ligand binding regions of ICOS are distributed between stretches of amino acids 49-52, 64-68, 75-78, and 114-119, a skilled artisan would conclude that at least the region of amino acids 49-119 is required for ligand binding, and that a fragment not comprising this region would not be expected to possess the claimed properties.

Applicants respectfully disagree. Given the level of skill in the art and the teachings of Applicants' specification, a person of ordinary skill in the art would have been able to make and use the polypeptides recited in the previous claims. To further prosecution, however, Applicants have removed the recitation of "a fragment of at least 15 amino acids of the extracellular domain" from claim 1. Thus, claim 1 recites a purified polypeptide consisting of a variant of a wild-type ICOS amino acid sequence, consisting of an extracellular domain of wild-type ICOS. As noted by the Examiner, Applicants' specification enables such a polypeptide.

In light of the above, Applicants respectfully request withdrawal of this rejection of claims 1, 3, 5, 7, and 24-26 under 35 U.S.C. § 112, first paragraph.

CONCLUSION

Applicants submit that claims 1, 3-7, and 24-26 are in condition for allowance, which action is respectfully requested. The Examiner is invited to telephone the undersigned agent if such would further prosecution.

Applicants believe that no fee is due. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

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